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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,072	04/06/2001	Melissa E. Scott	16528A039800	7264

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,072

Applicant(s)

SCOTT ET AL.

Examiner

Jeffrey Fredman

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-- Th MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 3-11, 14, 15, 18, 20-27, 29-44 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12, 13, 16, 17, 19, 28 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I, a biological cell and Species A, a change in capsule size in the paper filed November 20, 2003 is acknowledged.

Applicant did not elect the species A which was "a release of a detectable species from said capsule", which would include those claims drawn to cleavage by restriction enzymes, photocleaving groups, rupturable by heat, magnetic particles, or cleavage of B-galactosidase. Therefore, claims 20-22, 25-27, 29-44, 48-52 are not elected species and are withdrawn from examination. (With regard to claim 50, this claim is actually nonelected because the elected species I is a biological cell and this claim is drawn to peptides. The elected claims are therefore 1, 2, 12, 13, 16, 17, 19, 28, 45-47. Claims 3-11, 14, 15, 18, 20-27, 29-44 and 48-52 are non-elected.

2. However, this case is somewhat unusual in that the examiner believes certain embodiments would be free of the prior art. The examiner believes (but has not fully searched) that cleavage as in non-elected claims 20-22 would overcome the prior art. If the intelligent substance was better defined (ie as an antibody-antigen interaction, or as a B-galactosidase) and in which the indication involved the cleavage event such as is claimed in non-elected claims 20-22, 25, etc., this might direct the claims towards an element of the invention which is preferable to Applicant. Therefore, if Applicant wishes to alter the election from change in size to cleavage by a Markush group of methods such as enzymes, magnetic fields, etc. as claimed and place those elements in the

independent claim, the examiner would strongly consider such a request for rejoinder and shift in election to a different species.

Claim Rejections - 35 USC § 112

3. Claims 1, 2, 12, 13, 16, 17, 19, 28, 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the term "intelligent substance" in claim 1 and later claims. While the compound is supposed to be responsive to the environment, there is no clear delineation of which compounds meet the requirements for "intelligence" and which do not.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 12, 13, 16, 17, 28 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer (U.S. Patent 5,501,857).

Zimmer teaches a method of claims 1 and 45 which comprises:

a) forming a plurality of capsule containing a candidate species in an inner

capsule which is a formulation of five different bacterial cells including Lactobacillus acidophilus (see column 12, lines 40-49) as well as candidate species that are isolated

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from the bacterial cells in an outer capsule including vitamin A, vitamin D, vitamin E and other compounds (see column 12, lines 49-62),

b) imposing a condition on the capsule by placing the capsules in fresh cow rumen contents (see example 6, lines 10-67),

c) monitoring the capsule for the change in size (see column 17, lines 10-67 and table 4, where the capsule is reduced in size in the rumen contents).

With regard to claim 2, the target is biological cells including the *Lactobacillus acidophilus* (see column 12, lines 40-49).

With regard to claims 12 and 13, the *Lactobacillus* and other bacterial will be able, upon dissolution of the capsule, to interact with the list of vitamins at column 12, lines 49-62, some of which will function as agonists and some as antagonists, depending upon the pathway.

With regard to claims 16 and 17, the capsule changes in size by being reduced in size (see table 4).

With regard to claim 28, the candidate species of vitamin A, for example, is a chemical compound (see column 12, lines 49-62).

With regard to claims 46 and 47, the candidate species in the outer capsule comprise multiple distinct molecular species such as vitamin A, vitamin D, vitamin E and other compounds (see column 12, lines 49-62).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
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